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Case No. 94-105 RRM

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### DECLARATION OF DR. JED B. GORLIN

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I, JED B. GORLIN, M.D., do hereby declare:

1. I am Acting Director of the Transfusion Service and Director, Clinical Cryobiology Laboratory, Division of Hematology at Children's Hospital in Boston, Massachusetts, and Instructor in Pediatrics at Harvard Medical School. A copy of my curriculum vitae is attached hereto as Exhibit A.

2. I am a principle investigator of a clinical protocol that includes the use of the CellPro CEPRATE® system. We are investigating the use of stem cell selection in double autologous peripheral blood stem cell transplants in children with high risk neuroblastoma and sarcomas. Currently, children with these conditions have a less than 20% chance of long term survival when treated with conventional chemotherapy. Others have demonstrated that relapse following autologous transplants can be contributed to by tumor contamination of the reinfused hematopoietic stem cell product. We are hoping that by use of the positive selection column that we can achieve some degree of tumor purging, a concept supported by in vitro analyses. Hence, we are concerned that the current patent dispute might adversely affect our ability to continue this important clinical study.

3. Our current study in children with high risk neuroblastoma and sarcoma is a feasibility study to determine

whether use of the CellPro system in these patients will result in safe transplants and remove tumor cells in the material reinfused into these patients. The logical outcome of such a pilot study will be to elevate the study to a randomized control trial to determine efficacy of the procedure, i.e., whether this is the best treatment for these patients or whether it is better than conventional treatments.

4. I understand that our supply of the CellPro device may be limited to the volume we were using as of March 1997. Such a restriction would adversely impact our ability to advance our pilot study in neuroblastoma to the randomized trial, thereby limiting the availability of this potentially life sustaining technology to these desperately ill children.

I declare under penalty of perjury that the foregoing is true and correct.

Executed at Boston, Massachusetts, this 18<sup>th</sup> day of April 1997.



Jed B. Gerlin, M.D.